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K073223

510(k) SUMMARY

510(k) Owner:	Alfa Wassermann Diagnostic Technology, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Dennis Taschek Phone: 973-852-0177 Fax: 973-852-0237
Date Summary Prepared:	June 19, 2008
Device:	Trade Name: S-Test CO2 Reagent cartridge Common/Classification Name: Carbon dioxide test system (21 C.F.R. § 862.1160) Product Code KHS Classification: Class II
Predicate Devices:	Manufacturers for analyzer/reagent system predicates are: 1. ACE plus ISE/Clinical Chemistry System ACE Carbon Dioxide Reagent (K931786) 2. Ortho Clinical Diagnostics Fusion Clinical Chemistry Analyzer Carbon Dioxide Reagent (K946090) 3. Piccolo® xpress Chemistry Analyzer Carbon Dioxide Reagent (K942782)
Device Description:	The S-Test Carbon dioxide (CO2) reagent cartridge, used with the S40 Clinical Analyzer, is intended for quantitative *in vitro* diagnostic determination of CO2 in serum or heparin plasma based on a photometric test measuring the formation of an enzymatic cofactor in a coupled enzymatic reaction.
Intended Use:	The S-Test Carbon Dioxide Reagent is intended for the quantitative determination of carbon dioxide concentration in serum or heparin plasma using the S40 Clinical Analyzer. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Technological Characteristics:	The S-Test CO2 Reagent is contained in a bi-reagent cartridge. Reagent 1 contains water and a preservative. Reagent 2 contains phosphoenolpyruvate, nicotinamide adenine dinucleotide analog (reduced), phosphoenol pyruvate carboxylase, and malate dehydrogenase.
Performance Data:	Performance data on the S-Test CO2 included precision, accuracy, and sensitivity data. Precision: In testing conducted at three CO2 levels for 21 days, the within-run CV ranged from 1.7 to 3.0%, and total CV ranged from 5.7 to 6.7%. In precision studies at three separate Physician Office Laboratory (POL) sites and in-house over five or more days, the within-run CV ranged from 1.3 to 6.6% and total CV ranged from 2.0 to 6.6%. Accuracy: In the correlation study, 94 samples with CO2 values ranging from 6.0 to 41.8 mEq/L were assayed on the S40 Clinical Analyzer using S-Test CO2 and a comparison method. Least-squares regression analysis yielded a correlation coefficient of 0.984, a standard error estimate of 1.1, a confidence interval slope of 0.940 to 1.029, and a confidence interval intercept of -0.6 to 1.5. In patient correlation studies at three separate POL sites using the S40 Clinical Analyzer and a comparative method, least-squares regression analysis yielded correlation coefficients ranging from 0.937 to 0.980, standard error estimates ranging from 1.40 to 2.65, confidence interval slopes ranging from 0.880 to 1.080, and confidence interval intercepts ranging from -1.73 to 2.03. Sensitivity: The detection limit was 5 mEq/L.
Conclusions:	Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Alfa Wassermann Diagnostic Technologies, Inc.
c/o Mr. Daivd Slavin
Vice President, Quality and Regulatory Affairs
4 Henderson Drive
West Caldwell, NJ 07006

Re: k073223/S1
Trade/Device Name: S Test Carbon Dioxide (CO2) Reagent Cartridge
Regulation Number: 21 CFR 862.1160
Regulation Name: Bicarbonate/carbon dioxide test system
Regulatory Class: Class II,
Product Code: KHS
Dated: November 15, 2007
Received: November 15, 2007

Dear Mr. Slavin

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K073223

Device Name: S-Test Carbon Dioxide (CO2)

Indications for Use: The S-Test Carbon Dioxide Reagent is intended for the quantitative determination of carbon dioxide concentration in serum or heparin plasma using the S40 Clinical Analyzer. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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